

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

22-MD-3050 (KPF)

CHANTIX (VARENICLINE)
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION
(NO. II)

This Document Relates to All Actions

STIPULATION AND PROTECTIVE ORDER

Pursuant to the stipulation of the Parties, as modified by this Court, the following Order shall govern the treatment of documents and information designated as confidential in connection with the above-captioned action and any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned there (collectively, the “MDL proceeding”):

I. PURPOSES AND LIMITATIONS

The subject matter of the MDL proceeding involves confidential materials and business practices. Disclosure and discovery activity in the MDL proceeding therefore may involve production of confidential, proprietary, or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation may be warranted. The information likely to be the subject of the disclosure and discovery activity in this MDL proceeding also may involve unique risks related to privacy, data security, data governance, and data management that will be greater than in most cases. The Parties acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords from public disclosure and use extends only to the limited information or items that are entitled to confidential treatment under the applicable legal principles.

II. DEFINITIONS

A. “Parties” means Plaintiffs Juan Abreu, Mary Allen, Theresa Baptiste, Timothy Bleeker, Harold Bradley, Sharon Carroll, Karen Duff, Albert Edwards, Tara Evans, Lillian Forrest, Kimberly Hill, Valerie Hogue, Douglas Houghton, James Jacobson, Tammy LaMotte, Kathleen Lima, Clarence Massey, Debroah Seeley, Daniel Spence, Hazel Taylor, Carita Thompson, Daphne Walter, Shannon Webb, County of Monmouth, MSP Recovery Claims Series 44 LLC, MSP Recovery Claims, Series LLC, Ohio Carpenters’ Health Fund (collectively “Plaintiffs”) and Defendant Pfizer Inc. (“Pfizer”) named in the Consolidated Master Class Action Complaint (ECF No. 40) and any person or entity that may be added to any subsequently filed complaint in this MDL proceeding.

B. “Appointed Counsel” means those attorneys and firms appointed who have formally appeared in the MDL proceedings on behalf of the Plaintiffs and counsel of record for Pfizer and their firms.

C. “Confidential Information” means any information (regardless of how it is generated, stored, or maintained) or tangible things:

1. that may reveal a trade secret or other confidential research, development, financial, data security information, network security details and diagrams;
2. that may reveal information that is not commonly known by or available to the public and derives value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain value from its disclosure or use;
3. that contains information that reveals Personally Identifiable Information, as defined below, or personal or private financial information (collectively “Sensitive Information”);
4. the disclosure of which is reasonably likely to result in unauthorized access of Sensitive Information;

5. that is Protected Health Information (“PHI”), as that phrase is defined in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), Pub. L. 104-191, and the regulations promulgated thereunder; or

6. any other material that is confidential pursuant to applicable law.

D. “Highly Confidential Information” means any Confidential Information, such as Sensitive Information, corporate network security details and other security information, competitively sensitive information, or any other information the disclosure of which to another party or non-party would create a risk of serious harm that could not be avoided by less restrictive means.

E. “Personally Identifiable Information” (PII), for purposes of this Order, includes, but is not limited to addresses, phone numbers, e-mail addresses, driver’s license numbers or other state identification numbers, social security numbers, tax identification numbers, payment card numbers, financial account numbers, passport numbers, or a foreign government equivalent of any of these numbers or identifiers or any other information that can reasonably identify an individual.

The Parties recognize that other personal data (*e.g.*, name, citizenship, birth date, spousal and familial information), particularly in combination with one another, may reveal sensitive PII and, for purposes of this Order, PII also includes such data when in combination with any other Sensitive Information.

F. “Privileged Material” means any document, information, or tangible thing that is, or that the Producing Party asserts is, protected from disclosure by a privilege or other immunity from discovery, including, without limitation, the attorney-client privilege, the work product immunity, or the joint defense or common interest privilege.

G. “Producing Party” or “Designating Party” means the party or third party that produced the Protected Material.

H. “Protected Material” means any document, information, or tangible thing which has been designated as “Confidential” or “Highly Confidential” pursuant to this Protective Order. Documents that quote, summarize, or contain Confidential Information or Highly Confidential Information (*e.g.*, discovery responses, transcripts, and court filings) may be accorded status as Protected Material, but, to the extent reasonably feasible, shall be prepared in such a manner that the Confidential Information or Highly Confidential Information is provided separately from that not entitled to protection.

III. DESIGNATING PROTECTED MATERIAL

A. The Producing Party has an obligation to stamp documents “Confidential” or “Highly Confidential” in good faith and must take care to limit any such designation to specific material that qualifies under the appropriate standards. The Parties shall make Confidential and Highly Confidential designations in good faith to ensure that only those documents or testimony that merit Confidential or Highly Confidential treatments are so designated. Either designation may be withdrawn by the Designating Party.

B. The Producing Party must designate for protection only those parts of material, documents, items, or oral or written communications that qualify – so that other portions of the material, documents, items, or communications for which protection is not warranted are not swept unjustifiably within the ambit of this Order. Mass, indiscriminate, or routinized designations are prohibited. If a Producing Party believes that information or items that it designated for protection do not qualify for protection at all, or do not qualify for the level of

protection initially asserted, that Producing Party must promptly notify all other Parties that it is withdrawing the mistaken designation.

C. Third parties producing documents in the course of this MDL proceeding may designate documents as “Confidential” or “Highly Confidential” subject to the same protections, obligations, and constraints as the Parties to the action. A copy of this Protective Order shall be served along with any subpoena or document request served on third parties in connection with this action. All documents produced by such third parties shall be treated as “Highly Confidential” for a period of 30 days from the date of their receipt, and during that period any party or the third party may designate such documents as “Confidential” or “Highly Confidential” pursuant to the terms of the Protective Order.

IV. SCOPE

A. The protections conferred by this Protective Order cover not only Protected Material, but also (1) any information copied or extracted from Protected Material; (2) all copies, derivations, abstracts, excerpts, summaries, or compilations of Protected Material; and (3) any testimony, conversations or presentations by Parties or their counsel that might reveal Protected Material.

B. However, the protections conferred by this Protective Order do not cover the following information: (1) any information that is in the public domain at the time of disclosure to a receiving party or becomes part of the public domain after its disclosure to a receiving party as a result of publication not involving a violation of this Order, including becoming part of the public record through trial or otherwise; and (2) any information known to the receiving party prior to the disclosure or obtained by the receiving party after the disclosure from a source who

obtained the information lawfully and under no obligation of confidentiality to the Designating Party.

C. The entry of this Protective Order does not prevent any party from seeking a further order pursuant to Federal Rule of Civil Procedure 26(c) or any applicable state procedural rule or provision governing the terms on which disclosure or discovery may be had. Any use of Protected Material at trial shall be governed by a separate agreement or order.

V. DURATION

Even after final disposition of this MDL proceeding, the confidentiality obligations imposed by this Protective Order shall remain in effect until a Designating Party agrees otherwise in writing or a court order directs otherwise. Final disposition shall be deemed to the later of (1) dismissal of all claims and defenses in this action, with or without prejudice; or (2) final judgment herein after the completion and exhaustion of all appeals, rehearings, remands, trials, or reviews of this action, including the time limits for filing any motions or applications for extension of time pursuant to applicable law.

VI. NON-DISCLOSURE OF PROTECTED MATERIAL

A. Except with the prior written consent of the Producing Party, as provided in this Order, or as may be subsequently ordered by the Court, Protected Material may not be disclosed by a non-Producing Party to any person except as described below.

B. “Confidential Information” may be disclosed by a non-Producing Party only to:

1. The Parties to this MDL proceeding who are individuals, or for Parties who are entities, their officers, directors, and employees, only to the extent reasonably necessary to provide assistance with the MDL proceeding¹;

¹ The Parties will submit a separate protocol at a later date governing the proceedings at trial, including the scope of and procedures associated with showing Confidential Information to witnesses at trial.

2. Appointed Counsel and counsel for the Parties in the MDL proceeding, including the in-house lawyers of such Parties and the partners, associates, contract attorneys, secretaries, paralegal assistants, employees of such counsel, only to the extent reasonably necessary to render professional services in the MDL proceeding, and for use exclusively in these actions (and for no other purpose);

3. Judges, the jury, court reporters, court personnel, and videographers present at trial, hearings, arguments, depositions, and any other judicial proceedings held in this MDL proceeding;

4. Any deponent or witness at deposition, or hearing, for whom it appears on the face of the document that the deponent or witness authored or received a copy of the document or is employed by the Producing Party;

5. Other persons who may be designated by written consent of the Producing Party or pursuant to Court order, but only for purposes of this MDL proceeding and for no other purpose, provided the person signs the “Acknowledgement and Agreement to be Bound” (the “Acknowledgement,” attached as Exhibit A);

6. Witnesses during depositions or at a hearing, who have signed the Acknowledgment.

7. Persons who Appointed Counsel have a good faith basis to believe received the document or who had access to or the authority to access or obtain the document in the normal or authorized course of business and who have signed the Acknowledgment;

8. Mock jurors, provided the person signs the Acknowledgement;

9. Any mediator who is assigned to hear this matter, and his or her staff, provided the person signs the Acknowledgement;

10. Consultants or experts retained for the purpose of assisting Appointed Counsel in this MDL proceeding who have signed the Acknowledgement and who are not current employees of a competitor of a party and have not, at the time of retention, agreed to become an employee of a competitor of a party; and

11. Third-party contractors retained for the purpose of organizing, filing, coding, converting, storing, or retrieving data or designing database programs for handling Protected Material who have signed the Acknowledgement.

C. Protected Material designated as “Highly Confidential Information” may be disclosed by a non-Producing Party only to:

1. Persons designated in paragraphs B.2-B.11, as well as Appointed Counsel, counsel of record, and the partners, associates, contract attorneys, secretaries, paralegal assistants, and employees of such counsel, to the extent reasonably necessary to render professional services in the litigation.

2. Persons designated in paragraph B.1, not otherwise included in C.1, after they have signed the Acknowledgement and only to the extent it is reasonably necessary to prosecute their claims.

D. Counsel for all persons receiving Protected Material in accordance with paragraphs B.5-B.8 or C.2 shall be responsible for obtaining, prior to disclosure and as a condition thereof, an Acknowledgement executed by the person to whom the counsel discloses the Confidential or Highly Confidential Information. Each non-party witness to whom Confidential or Highly Confidential Information is disclosed shall be advised that the Court has entered a Protective Order to limit disclosure of Confidential and Highly Confidential Information, be provided a copy of the Protective Order, and be asked to sign the Acknowledgement. If a non-party witness has refused to sign the Acknowledgement, then the party wishing to show the document must meet and confer with the Producing Party and/or seek the Court's guidance. The Parties will attempt to obtain a non-party's Acknowledgement prior to taking her/his deposition.

E. A recipient of Protected Material shall keep the material in a secure manner that ensures that access is limited to the persons authorized by this Protective Order. Any copies, excerpts, or compilations of Protected Material, whether in oral or written form, shall be subject to this Protective Order to the same extent as the Protected Material itself, and, if in written form, must be labeled as "Confidential" or "Highly Confidential". A recipient shall not duplicate any Protected Material except for use as working copies and for filing in court. Any litigation support site used to maintain Confidential or Highly Confidential Information shall apply standard industry practices regarding data security, including but not limited to application of access control rights to those persons entitled to access Confidential or Highly Confidential material under the Protective Order. Any Confidential or Highly Confidential Information that is in an electronic format shall be stored only on devices (*e.g.*, laptop, tablet, smartphone, USB drive) that are password protected and/or encrypted with access limited to persons entitled to access

Confidential Information under the Protective Order. If the user is unable to password protect and/or encrypt the device, then the Confidential or Highly Confidential Information shall be password protected and/or encrypted at the file level. When emailing Confidential or Highly Confidential Information, it shall be encrypted or sent via a password protected link and the password or encryption key should not be sent in the same email.

F. The Producing Party may redact PII and any other information required to be withheld from disclosure by 21 C.F.R. § 20.693, HIPAA, and other related and applicable laws and regulations.

G. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as Confidential Information. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

VII. DE-DESIGNATION AND CHALLENGING OF PROTECTED MATERIAL

A. Any party may request a change in the designation of any information designated as “Confidential” or “Highly Confidential.” Any Protected Material shall be treated as designated until the change is completed. If the requested change in designation is not agreed to, the party asserting that the material is confidential shall have the burden of proving that the information in question is within the scope of protection afforded by Fed. R. Civ. P. 26(c) and this Protective Order.

B. Any party or non-party may challenge a designation of confidentiality at any time. Unless a prompt challenge to a Designating Party’s confidentiality designation is necessary to

avoid foreseeable, substantial unfairness, unnecessary economic burdens, or a significant disruption or delay of the MDL proceeding, a party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed.

C. The party or non-party challenging a confidentiality designation shall do so in writing to the Designating Party and identify each challenged document by Bates number or otherwise specifically describe the document challenged and set forth the specific reasons why it does not believe the confidentiality designation is appropriate. The parties/non-parties shall attempt to resolve each challenge in good faith and must begin the process by conferring directly within 14 days of the date of service of the written notice. The party or non-party challenging a confidentiality designation may proceed to the next stage of the challenge process only if it has engaged in this meet and confer process first or establishes that the Designating Party is unwilling to participate in the meet and confer process in a timely manner.

D. Within 14 days of completing the meet and confer process, the party or non-party asserting confidentiality must move the Court for relief. All parties and non-parties shall continue to afford the material in question the level of protection to which it is entitled under the Designating Party's designation until the Court rules on the challenge.

VIII. CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION IN DEPOSITIONS

A. If a party, the current employee of a party, or anyone represented by counsel for a party, is noticed for deposition, that party's counsel is responsible for providing a copy of this Protective Order to the witness and obtaining the witness's signature on the Acknowledgement prior to the deposition as required in Section VI above. If a non-party is subpoenaed for deposition,

the counsel issuing the subpoena is responsible for providing a copy of this Protective Order to the witness and attempting to obtain a signed Acknowledgement as required in Section VI above.

B. Parties and deponents may, within 30 days after receiving the deposition transcript from the court reporter, designate pages and lines of the transcript (and exhibits thereto) as “Confidential” or “Highly Confidential” by underlining or otherwise designating the portions of the pages that are confidential. (Documents marked as deposition exhibits that have been previously designated for protection under this Protective Order do not need to be re-designated in order to maintain their designation.) The Parties and the court reporter shall thereafter mark such pages in all copies of the transcript with the legend, “CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER” or “HIGHLY CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER” and will note on the cover page of any such deposition the following legend: “Certain Designated Pages of this Deposition are Confidential and Subject to a Protective Order.” Until expiration of the 30-day period, the entire deposition transcript will be treated as Highly Confidential pursuant to this Protective Order.

IX. SUBPOENAS OR LEGAL PROCESS CALLING FOR DISCLOSURE OF PROTECTED MATERIAL

If a party receives a subpoena or other legal process which calls for disclosure of any Protected Material designated as Confidential or Highly Confidential Information by another party, then the party from whom disclosure is sought shall give prompt written notice (including a copy of such subpoena or other legal process) to counsel for the Designating Party, and shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information until 21 days after providing notice to the Designating Party.

X. FILING AND USE OF PROTECTED MATERIAL

A. Any document, material or other information entitled to protection under this Protective Order that is submitted to the Court in support of a pleading, or introduced at a hearing, trial, or other proceeding in this action must comply with the Southern District of New York's local rules and procedures for filing a document under seal. Specifically, Counsel may e-file (1) a motion to seal, which may be e-filed as a public motion or a sealed motion, (2) a redacted version of each document sought to be sealed, which shall be e-filed as a public document, (3) unredacted copies of each document sought to be sealed, which shall be e-filed as sealed motions or sealed documents, and (4) any memorandum or other documents supporting the assertion that grounds exist for sealing the documents sought to be sealed, which may be e-filed as public or sealed documents. Upon submission by the party of a motion to seal, the contents of any sealed motion or sealed document shall be treated as sealed unless the motion to seal is denied or until otherwise directed by the Court.

Alternatively, Counsel may e-file a motion to seal, which may be e-filed as a public motion or a sealed motion, along with a memorandum and supporting documents, without the documents sought to be sealed. If the Court grants the motion to seal in whole or in part, counsel shall e-file as public documents redacted copies of any documents required by the Court's sealing order, and shall e-file as sealed documents, unredacted copies of any motions or documents ordered sealed but not previously e-filed.

Lastly, Counsel may seek permission of the presiding Judge to submit the documents sought to be sealed for in camera consideration. If the Judge agrees to review documents in camera, counsel shall submit to Chambers and shall serve on all counsel of record copies of the documents sought to be sealed and shall e-file a motion to seal, a memorandum and supporting documents. If counsel want the motion to seal, memorandum or supporting documents to be

considered as documents to be sealed, counsel shall e-file those submissions as sealed motions and/or sealed documents and their contents shall be treated as sealed unless the motion to seal is denied or until otherwise directed by the Court. If the Court grants the motion to seal in whole or in part, counsel shall e-file any redacted copies of the documents required by the Court's sealing order and shall e-file the unredacted documents as sealed documents.

B. Any documents submitted to the Court and filed under seal will not be available for public viewing. These documents shall only be available for viewing by Court personnel and Appointed Counsel for the parties and shall be subject to the restrictions on Confidential and Highly Confidential Information under this Protective Order, as applicable.

C. Confidential or Highly Confidential material shall presumptively be entitled to continued protection until such time as determined otherwise by the Court.

D. The Parties are instructed to use their best efforts to limit the filing of Confidential or Highly Confidential Information under seal to those situations where such filing is necessary to the resolution of a motion or other matter before the Court. Filing Confidential or Highly Confidential Information under seal imposes a burden on the Court and should be avoided wherever possible.

E. A party who seeks to introduce Confidential or Highly Confidential Information at a hearing, or other proceeding, shall advise the Designating Party at least 3 days in advance of the hearing, or other proceeding, so that the Parties may notify the Court of their intention to introduce such information. In light of the burden that the introduction of designated material imposes upon the Court, the Parties are instructed to use their best efforts to limit the introduction of such material and the continued designation of such material as confidential in the event its introduction is necessary. If the Designating Party requests the protection be continued, the party who seeks to

introduce the material at a hearing, trial, or other proceeding will submit the information to the Court, which will review the information, *in camera*, to determine if the information is entitled to continued protection. Unless expressly ordered to be sealed by the Court, any material entitled to protection from disclosure under this Protective Order shall be viewable only by Court personnel and Appointed Counsel for the Parties and remain subject to the restrictions on Confidential and Highly Confidential Information under this Protective Order, as applicable.

F. In the event any case is remanded, Protected Material shall be filed under seal in the transferor court according to the Electronic Case Filing procedures and other applicable rules of the transferor district and shall remain restricted in the Clerk's office of the transferor court so long as they retain their confidential status.

XI. PROPER USE OF PROTECTED MATERIAL

Persons obtaining access to Protected Material pursuant to this Protective Order shall use the information in connection with this litigation only — including appeals and retrials — and shall not use such information for any other purpose, including business, governmental, commercial, or administrative or judicial proceedings, unless otherwise required by applicable law.

XII. NON-TERMINATION

The provisions of this Protective Order shall not terminate at the conclusion of this action or any or all of the individual actions coordinated or consolidated herein. Within 90 days after final disposition, as defined in Section V, Protected Material and all copies of same (other than exhibits of record) and information integrated into work product shall be returned to the Producing Party or destroyed.

Any return shipping done at the request of the Producing Party shall be done at the expense of the Producing Party. Notwithstanding the foregoing, counsel for all Parties may keep one copy

of any transcripts, pleadings and exhibits and shall maintain them in confidence. Upon written request, all counsel of record shall make certification of compliance herewith and shall deliver the same to counsel for the Producing Party not more than 100 days after final disposition.

XIII. NON-WAIVER OF PRIVILEGES

A. This Protective Order is entered pursuant to and invokes the protections of Federal Rule of Evidence 502(d). Except as otherwise set forth below, the provisions in Rule 502(b) will apply to the disclosure of documents or information (“Discovery Material”) in this action, other than an intentional disclosure. A Producing Party may, at its sole option, produce such materials without detailed, or any, review to determine whether the production includes Privileged Material.

B. This Stipulation and Order does not preclude a Party from intentionally waiving any claims of privilege or protection.

C. The provisions of Rule 502(a) of the Federal Rules of Evidence apply when a Party uses Privileged Material or Protected information to support a claim or defense, when a Party uses Privileged Material or Protected Information during a deposition without the assertion of a contemporaneous objection, when a Party intentionally discloses Privileged Material or Protected Information to a third party, including the Court (*e.g.*, in connection with or support of a filing), or when a Party makes selective disclosures of documents for any other purpose. This paragraph does not preclude a Party from arguing that waiver was made under any applicable rule of law.

D. The Parties may stipulate without the need for Court approval to narrow or extend the time periods specified in this Stipulation and Order.

XIV. CLAWBACK OF DISCLOSURE

A. A Producing Party that determines that it made a disclosure of Confidential or Highly Confidential Information that was not marked as such or Privileged Material in this

Litigation shall promptly notify the Receiving Party following discovery of the production, and the Receiving Party (the “Returning Party”) shall:

1. in the case of Privileged Material: (i) immediately cease the review and use of the disclosed document or information, except to the extent necessary to submit to Court for *in camera* review as part of a privilege challenge; (ii) if the Receiving Party does not challenge the assertion, return, sequester, or destroy the disclosed document or information forthwith, as well as any and all copies thereof; and (iii) if the Receiving Party does not challenge the assertion, destroy, or sequester any references to the erroneously or inadvertently disclosed document or its contents, to the extent such references exist in other materials prepared by the Returning Party; or

2. in the case of a Confidential or Highly Confidential document, shall mark it and all copies “CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER” or “HIGHLY CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER” at the expense of the Producing Party and treat the document as Protected Material under the terms of this Order. A party may sequester a Document if challenging a clawback request.²

B. Upon request of the disclosing Party, the Returning Party must provide to the disclosing Party a certification of counsel that all of the disclosed discovery has been returned, sequestered, or destroyed subject to the terms of this paragraph. The Receiving Party is not required to return, sequester, or destroy any discovery item claimed to be Privileged Material if

² Copies of disclosed Confidential Information, Highly Confidential Information or Privileged Material that have been stored on electronic media that are not reasonably accessible, such as disaster recovery backup media, are adequately sequestered as long as they are not restored. If such data is restored, the Returning Party must take steps to re-sequester the restored disclosed Confidential Information, Highly Confidential Information, or Privileged Material.

the Receiving Party intends to move the Court for a ruling that the document was never privileged or protected, unless and until the Court determines the document is privileged or protected.

If any produced Privileged Material, Confidential Information, or Highly Confidential Information has been provided to a non-party by a non-Producing Party, the non-Producing Party will use all reasonable efforts to secure the return of the Privileged Material (and the destruction of any references thereto) and/or proper designation of the Confidential Information or Highly Confidential Information, including reminding the non-party of its obligation to adhere to the terms of this Protective Order that the non-party agreed to by executing the Acknowledgement attached as Exhibit A.

C. Notice of disclosure shall apply to all copies of the document disclosed.

D. If a receiving party disputes the Producing Party's privilege claim, the receiving party shall notify the Producing Party of the dispute and the basis therefore in writing within three business days of receipt of the notification of inadvertently produced material subject to a claim of privilege or other protection. However, to the extent that a Producing Party seeks to claw back more than 100 documents, the receiving party shall be provided an additional ten business days to review such documents and dispute the privilege claims asserted over them. The Producing Party and receiving party thereafter shall meet and confer in good faith regarding the disputed claim within ten business days. In the event that the Producing Party and receiving party do not resolve their dispute, the party challenging privilege must bring a motion for a determination of whether a privilege applies within ten days of the determination that no resolution will be achieved. If such a motion is made, the moving party shall submit to the Court for *in camera* review a copy of the inadvertently produced material in connection with its motion papers.

E. A party is not precluded by this Protective Order from arguing that a privilege or protection has been waived for reasons other than the inadvertent production of a document or information subsequently clawed back in accordance with the terms of this Protective Order.

F. Notwithstanding the foregoing, the Parties agree that any document used by any Party in a deposition, expert report, or court filing in this action (with the exception of a motion pursuant to Section XIII.D. of this Stipulated Protective Order), that a Producing Party does not claw back within 7 calendar days of its use, (“Used Document”) shall not be eligible for clawback of that document under Sections XIII.A-D of this Stipulated Protective Order. Such ineligibility for clawback of that document under Sections XIII.A-D of this Stipulated Protective Order shall not result in a subject matter waiver in any other state or federal proceeding. The Producing Party reserves its rights to utilize FRE 502(b) and the Receiving Party reserves its rights under FRE 502(b), including but not limited to establishing whether and to what extent a court order recognizing waiver of privilege under FRE 502(b) with respect to a document effects a subject matter waiver.

XV. MODIFICATION PERMITTED

Any party for good cause shown may apply to the Court for modification of this Protective Order. This Protective Order shall remain in full force and effect and each person subject to this Order shall continue to be subject to the jurisdiction of this Court for the purposes of this Protective Order, in perpetuity, and the Court shall not be divested of jurisdiction of any person or of the subject matter of this Protective Order by the occurrence of conclusion of this case, or by the filing of a notice of appeal, or other pleading which would have the effect of divesting this Court of jurisdiction of this matter generally.

IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

DATED: 8/21/24

/s/ Loren H. Brown

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This confidentiality agreement does not bind the Court or any of its personnel. The Court can modify this stipulation at any time. The Court will retain jurisdiction over the terms and conditions of this agreement only for the pendency of this litigation. Any party wishing to make redacted or sealed submissions shall comply with Rule 9 of this Court's Individual Rules of Civil Procedure.

Date: August 22, 2024
New York, New York

SO ORDERED.

A handwritten signature in blue ink, reading "Katherine Polk Failla".

HON. KATHERINE POLK FAILLA
UNITED STATES DISTRICT JUDGE

ATTACHMENT A

ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

_____ declares that:

I reside at _____, in the City of _____, County of _____, State of _____. My telephone number is: _____. I am currently employed by _____, located at _____ and my current job title is _____.

I have read and understand the terms of the Protective Order dated _____, filed in *In re: Chantix (Varenicline) Marketing, Sales Practices and Products Liability Litigation (No. II)* (Case No. 3:22-md-3050) currently pending in the United States District Court for the Southern District of New York. I agree to comply with and be bound by the provisions of the Protective Order. I understand that any violation of the Protective Order may subject me to sanctions by the Court.

I shall not disclose in any manner any information that is subject to this Protective Order to any person or entity except in strict compliance with the provisions of this Order. I shall not divulge any documents, or copies of documents, designated “Confidential” or “Highly Confidential” obtained pursuant to such Protective Order, or the contents of such documents, to any person other than those specifically authorized by the Protective Order. I shall not copy or use such documents except for the purposes of this action and pursuant to the terms of the Protective Order.

As soon as practical, but no later than 30 days after final disposition of this action, I shall return to the attorney from whom I have received them any documents in my possession designated “Confidential” or “Highly Confidential,” and all copies, excerpts, summaries, notes, digests,

abstracts, and indices that contain Confidential or Highly Confidential Information (except those documents that reflect my attorney work product); or certify that I have destroyed any documents in my possession designated “Confidential” or “Highly Confidential,” and all copies, excerpts, summaries, notes, digests, abstracts, and indices that contain Confidential or Highly Confidential Information (except those documents that reflect my attorney work product).

I submit myself to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of enforcing or otherwise providing relief relating to the Protective Order.

This ____ day of _____, 202__.

(Printed Name)